High-Flux Dialysis Membrane with Improved Separation Behaviour

Claims

1. A hydrophilic, water-wettable, semipermeable hollow-fibre membrane, particularly for hemodialysis, hemodiafiltration or hemofiltration, based on a synthetic hydrophilic polymer that forms the membrane structure or a combination of a synthetic first polymer that forms the membrane structure and a hydrophilic second polymer, wherein the synthetic first polymer in the combination can be hydrophilic or hydrophobic and the hydrophilic second polymer ensures the hydrophilicity of the hollow-fibre membrane if the synthetic first polymer is hydrophobic, the membrane possessing an open-pored, integrally asymmetric structure across its wall, a porous separating layer of thickness 0.1 to 2 µm on its inner surface facing the lumen, and an open-pored supporting layer adjoining the separating layer, the hollow-fibre membrane having an ultrafiltration rate in albumin solution in the range of 25 to 60 ml/(h·m²·mmHg) and, after prior drying, a minimum sieving coefficient for cytochrome c of 0.8 combined with a maximum sieving coefficient for albumin of 0.005, whereby the hollow-fibre membrane in the dry state is free from pore-stabilising additives in the membrane wall, characterised in that a polyelectrolyte with negative fixed charges is physically bound in the separating layer.

2. Hollow-fibre membrane according to Claim 1, characterised in that it comprises a hydrophobic first polymer that forms the membrane structure and a hydrophilic second polymer.

3. Hollow-fibre membrane according to Claim 2, characterised in that the hydrophobic first polymer is an aromatic sulfone polymer such as polysulfone, polyethersulfone, polyphenylenesulfone or polyarylethersulfone, a polycarbonate, polyimide, polyetherimide, polyetherketone, polyphenylene sulfide, or a copolymer or mixture of these polymers.

4. Hollow-fibre membrane according to Claim 3, characterised in that the hydrophobic first polymer is a polysulfone or a polyethersulfone.

5. Hollow-fibre membrane according to one or more of Claims 1 to 4, characterised in that the hydrophilic second polymer is polyvinylpyrrolidone, polyethylene glycol, polyvinyl alcohol, polyglycol monoester, polysorbate, carboxymethylcellulose, or a copolymer of these polymers.

6. Hollow-fibre membrane according to one or more of Claims 1 to 5, characterised in that the supporting layer extends from the separating layer across essentially the entire wall of the hollow-fibre membrane, has a sponge-like structure and is free from finger pores.

7. Hollow-fibre membrane according to one or more of Claims 1 to 6, characterised in that it has a minimum sieving coefficient for cytochrome c of 0.85.

8. Hollow-fibre membrane according to one or more of Claims 1 to 7, characterised in that it has a maximum sieving coefficient for albumin of 0.003.

9. Hollow-fibre membrane according to one or more of Claims 1 to 8 with an ultrafiltration rate in albumin solution in the range of 30 to 55 ml/(h·m²·mmHg).

10. Method for producing a hydrophilic, water-wettable, semipermeable hollow-fibre membrane, the method comprising the following steps:
    a. preparing a homogeneous spinning solution comprising 12 to 30 wt.%, relative to the weight of the spinning solution, of a synthetic hydrophilic polymer or 12 to 30 wt.%, relative to the weight of the spinning solution, of a synthetic first polymer in combination with 0.1 to 30 wt.%, relative to the weight of the spinning solution, of a hydrophilic second polymer, wherein the synthetic first polymer in the case of the combination can be hydrophilic or hydrophobic, and, if necessary, other additives in a solvent system,
    b. extruding the spinning solution through the annular slit of a hollow-fibre die to give a hollow fibre,
    c. extruding an interior filler through the central opening of the hollow-fibre die, the interior filler being a coagulation medium for the synthetic first polymer and comprising a solvent and a non-solvent for the synthetic first polymer,
    d. bringing the interior filler into contact with the inner surface of the hollow fibre to initiate coagulation in the interior of the hollow fibre and for formation of a separating layer on the inner surface of the hollow fibre and formation of the membrane structure,
    e. passing the hollow fibre through a coagulation bath to complete the formation of the membrane structure if necessary, and to fix the membrane structure,
    f. extracting the hollow-fibre membrane thus formed to remove the solvent system and soluble substances,
    g. drying the hollow-fibre membrane,

    characterised in that the interior filler contains a polyelectrolyte with negative fixed charges, wherein the proportion by weight of the polyelectrolyte is 0.025

to 5 wt.%, relative to the weight of the interior filler, and the steps of the method are to be carried out in such a way that a hollow-fibre membrane according to Claim 1 is obtained with a minimum sieving coefficient for cytochrome c of 0.80 combined with a maximum sieving coefficient for albumin of 0.005.

11. Method according to Claim 10, characterised in that the spinning solution contains 12 to 30 wt.%, relative to the weight of the spinning solution, of a hydrophobic first polymer in combination with 0.1 to 30 wt.%, relative to the weight of the spinning solution, of a hydrophilic second polymer.

12. Method according to Claim 11, characterised in that an aromatic sulfone polymer such as polysulfone, polyethersulfone, polyphenylenesulfone or polyarylethersulfone, a polycarbonate, polyimide, polyetherimide, polyetherketone, polyphenylene sulfide, or a copolymer or mixture of these polymers is used as the hydrophobic first polymer.

13. Method according to one or more of Claims 10 to 12, characterised in that polyvinylpyrrolidone, polyethylene glycol, polyvinyl alcohol, polyglycol monoester, polysorbate, carboxymethylcellulose, or a copolymer of these polymers is used as the hydrophilic second polymer.

14. Method according to one or more of Claims 10 to 13, characterised in that the solvent system comprises a polar aprotic solvent.

15. Method according to one or more of Claims 10 to 14, characterised in that the polyelectrolyte is selected from the group of polyphosphoric acids, polysulfonic acids or polycarboxylic acids.

16. Method according to Claim 15, characterised in that the polycarboxylic acids are homo- or copolymers of acrylic acid.

17. Method according to one or more of Claims 10 to 16, characterised in that the proportion by weight of the polyelectrolyte relative to the weight of interior filler is 0.01 to 1 wt.%